



# U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

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 Search

HOME

REGISTRATION

REPORTING

RESOURCES

ABOUT US


[RESOURCES > Title 21 USC Codified CSA > Section 823](#)

### Title 21 United States Code (USC) Controlled Substances Act

#### SUBCHAPTER I — CONTROL AND ENFORCEMENT

#### Part C — Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

#### §823. Registration requirements

##### (a) Manufacturers of controlled substances in schedule I or II

The Attorney General shall register an applicant to manufacture controlled substances in schedule I or II if he determines that such registration is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal and State laws relating to the manufacture, distribution, or dispensing of such substances;
- (5) past experience in the manufacture of controlled substances, and the existence in the establishment of effective control against diversion; and
- (6) such other factors as may be relevant to and consistent with the public health and safety.

##### (b) Distributors of controlled substances in schedule I or II

The Attorney General shall register an applicant to distribute a controlled substance in schedule I or II unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels;
- (2) compliance with applicable State and local law;
- (3) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (4) past experience in the distribution of controlled substances; and
- (5) such other factors as may be relevant to and consistent with the public health and safety.

##### (c) Limits of authorized activities

Registration granted under subsections (a) and (b) of this section shall not entitle a registrant to (1) manufacture or distribute controlled substances in schedule I or II other than those specified in the registration, or (2) manufacture any quantity of those controlled substances in excess of the quota assigned pursuant to section 826 of this title.

##### (d) Manufacturers of controlled substances in schedule III, IV, or V

The Attorney General shall register an applicant to manufacture controlled substances in schedule III, IV, or V, unless he determines that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule III, IV, or V compounded therefrom into other than legitimate medical, scientific, or industrial channels;
- (2) compliance with applicable State and local law;
- (3) promotion of technical advances in the art of manufacturing these substances and the development of new substances;
- (4) prior conviction record of applicant under Federal or State laws relating to the manufacture, distribution, or dispensing of such substances;
- (5) past experience in the manufacture, distribution, and dispensing of controlled substances, and the existence in the establishment of effective controls against diversion; and
- (6) such other factors as may be relevant to and consistent with the public health and safety.

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1/9

DEF-MDL-15985.00001

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3:18-CV-7591

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Admitted:

**(e) Distributors of controlled substances in schedule III, IV, or V**

The Attorney General shall register any applicant for interstate or foreign distribution of schedule III, IV, or V controlled substances. In determining the public interest, the following factors shall be considered:

1. Sworn statements of effect from citizens against diversion of particular controlled substances as well as other factors to make medical, scientific, and industrial supplies;
2. Compliance with applicable Federal and State law;
3. Prior record of compliance with applicable Federal and State law relating to the manufacture, distribution, or dispensing of controlled substances;
4. Past experience of the applicant in distributing controlled substances; and
5. Such other factors as may be relevant to and consistent with the public health and safety.

**(f) Research by practitioners; pharmacies; research applications; construction of Article 7 of the Convention on Psychotropic Substances**

The Attorney General shall register practitioners, including pharmacists, and institutions from pharmaceutical companies, to carry out research with controlled substances in schedule III, IV, and V, and shall notify the registration. If the drugs were not referred to another institution for dispensing, the institution may be the owner of the material if the applicant was the sole responsible person to research with respect to, and the regulations under the laws of the State in which the practice. The Attorney General may deny a registration for such registration if such institution is not registered at the Attorney General determines that the existence of such registration or institution would be inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

1. The experience of the institution, private state or local, or professional disciplinary authority;
2. The applicant's experience in dispensing or conducting research with respect to controlled substances;
3. The applicant's compliance with Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances;
4. Compliance with applicable Federal or State laws relating to controlled substances;
5. Compliance with any law which may threaten the public health and safety.

Separate registration shall be required for practitioners engaged in research with controlled substances in schedule III, IV, and V who are already registered under this part and the applicant, except for required registration applicant can be practitioners working for a institution with controlled substances in schedule III, IV, and V, and shall notify the registration. The applicant shall be responsible for the registration and competency of each practitioner requesting registration, as well as the institution's research project. The institution is responsible for the results of such research project, shall consult with the Attorney General with a written procedure to completely, adequate and appropriate of such controlled substances from legitimate medical or scientific use, registration for the purpose of dispensing, research with controlled substances, as well as the institution shall be required to be qualified by the Secretary may be denied by the Attorney General, except for a registration of the institution. This part, Article 7 of the Convention on Psychotropic Substances, shall be construed to prohibit, in approved Federal registration, research with controlled substances, except for the institution which is, and the institution may be, and the institution and other applicable provisions of this subchapter.

**(g) Practitioners dispensing narcotic drugs for narcotic treatment; annual registration; separate registration; qualifications; waiver**

1. Except as provided in paragraph 2, practitioners who dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment shall obtain a fully separate registration for that purpose. The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment if the:

- A. If the applicant is a practitioner who is determined by the Secretary to be qualified under standards established by the Secretary to be qualified to be treatment with respect to which registration is sought;
- B. If the Attorney General determines that the applicant will comply with standards established by the Attorney General respecting qualification of States of narcotic drugs for such treatment, and for the maintenance of records, and compliance with section 922 of this title on such drugs; and
- C. If the Secretary determines that the applicant will comply with standards established by the Secretary, after consultation with the Attorney General, respecting the quantities of narcotic drugs which may be provided for unsupervised use by individuals in such treatment.

2. As support to subparagraphs 1A and 1B, the requirements of paragraph 1C are waived in the case of the dispensing of drugs in the following circumstances: (1) a practitioner, through a pharmacist, schedules III, IV, or V controlled substances of such drugs if the institution meets the conditions specified in subparagraph B, and the conditions drugs or combinations of such drugs meet the conditions specified in subparagraph C.

3. For purposes of subparagraph A, the conditions specified in this subparagraph with respect to a practitioner are that, before the initial dispensing of narcotic drugs in schedule III, IV, or V controlled substances of such drugs to patients for maintenance or detoxification treatment, the practitioner is qualified by the Secretary, and the institution meets the conditions specified in subparagraph B, and the institution meets the conditions specified in subparagraph C, and that the institution is qualified to dispense narcotic drugs to patients.

The institution is a qualified institution as defined in subparagraph 1C.

With respect to paragraph 1A, in the institution will provide a training or certification of drugs, the practitioner has the appropriate training, and the institution meets the conditions specified in paragraph 1C.

1. All drugs approved by the Federal and State Administration for the treatment of opioid use disorder, including for maintenance, detoxification, and relapse prevention; and
2. Appropriate counseling and other appropriate medical services;
3. (1) The total number of practitioners of the practitioner shall be determined by the applicable number, except as provided in subclause (II); the applicant shall be:
- (II) The applicant shall be a practitioner who is qualified by the Secretary to be qualified to be treatment with respect to which registration is sought;
- (III) The Secretary may require the practitioner to be qualified;
- (IV) The Secretary may require the practitioner to be qualified.

4. For purposes of subparagraph A, the conditions specified in this subparagraph with respect to narcotic drugs in schedule III, IV, or V controlled substances of such drugs shall be:

The drugs are combinations of drugs, and the institution meets the conditions specified in Article 7 of the Convention on Psychotropic Substances, and the institution meets the conditions specified in Article 7 of the Convention on Psychotropic Substances.

5. The drugs are combinations of drugs shall be the subject of an adverse determination in purposes of this chapter, an adverse determination is a determination published in the Federal Register and made by the Secretary, after consultation with the Attorney General, that the use of the drugs or combinations of drugs for maintenance or detoxification treatment requires additional standard regarding the qualifications of practitioners to provide such treatment, or requires standards regarding the quantities of the drugs that may be provided for unsupervised use.



(D)(i) A waiver under subparagraph (A) with respect to a practitioner is not in effect unless (in addition to conditions under subparagraphs (B) and (C)) the following conditions are met:

- (I) The notification under subparagraph (B) is in writing and states the name of the practitioner.
- (II) The notification identifies the registration issued for the practitioner pursuant to subsection (f).
- (III) If the practitioner is a member of a group practice, the notification states the names of the other practitioners in the practice and identifies the registrations issued for the other practitioners pursuant to subsection (f).

(ii) Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B), the Attorney General shall assign the practitioner involved an identification number under this paragraph for inclusion with the registration issued for the practitioner pursuant to subsection (f). The identification number so assigned shall be appropriate to preserve the confidentiality of patients for whom the practitioner has dispensed narcotic drugs under a waiver under subparagraph (A).

(iii) Not later than 45 days after the date on which the Secretary receives a notification under subparagraph (B), the Secretary shall make a determination of whether the practitioner involved meets all requirements for a waiver under subparagraph (B) and shall forward such determination to the Attorney General. If the Secretary fails to make such determination by the end of the such 45-day period, the Attorney General shall assign the practitioner an identification number described in clause (ii) at the end of such period.

(E)(i) If a practitioner is not registered under paragraph (1) and, in violation of the conditions specified in subparagraphs (B) through (D), dispenses narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, the Attorney General may, for purposes of section 824(a)(4) of this title, consider the practitioner to have committed an act that renders the registration of the practitioner pursuant to subsection (f) to be inconsistent with the public interest.

(ii)(I) Upon the expiration of 45 days from the date on which the Secretary receives a notification under subparagraph (B), a practitioner who in good faith submits a notification under subparagraph (B) and reasonably believes that the conditions specified in subparagraphs (B) through (D) have been met shall, in dispensing narcotic drugs in schedule III, IV, or V or combinations of such drugs for maintenance treatment or detoxification treatment, be considered to have a waiver under subparagraph (A) until notified otherwise by the Secretary, except that such a practitioner may commence to prescribe or dispense such narcotic drugs for such purposes prior to the expiration of such 45-day period if it facilitates the treatment of an individual patient and both the Secretary and the Attorney General are notified by the practitioner of the intent to commence prescribing or dispensing such narcotic drugs.

(II) For purposes of subclause (I), the publication in the Federal Register of an adverse determination by the Secretary pursuant to subparagraph (C)(ii) shall (with respect to the narcotic drug or combination involved) be considered to be a notification provided by the Secretary to practitioners, effective upon the expiration of the 30-day period beginning on the date on which the adverse determination is so published.

(F)(i) With respect to the dispensing of narcotic drugs in schedule III, IV, or V or combinations of such drugs to patients for maintenance or detoxification treatment, a practitioner may, in his or her discretion, dispense such drugs or combinations for such treatment under a registration under paragraph (1) or a waiver under subparagraph (A) (subject to meeting the applicable conditions).

(ii) This paragraph may not be construed as having any legal effect on the conditions for obtaining a registration under paragraph (1), including with respect to the number of patients who may be served under such a registration.

(G) For purposes of this paragraph:

(i) The term "group practice" has the meaning given such term in section 1395nn(h)(4) of title 42.

(ii) The term "qualifying physician" means a physician who is licensed under State law and who meets one or more of the following conditions:

(I) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(II) The physician holds an addiction certification or board certification from the American Society of Addiction Medicine or the American Board of Addiction Medicine.

(III) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(IV) The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause. Such training shall include—

- (aa) opioid maintenance and detoxification;
- (bb) appropriate clinical use of all drugs approved by the Food and Drug Administration for the treatment of opioid use disorder;
- (cc) initial and periodic patient assessments (including substance use monitoring);
- (dd) individualized treatment planning, overdose reversal, and relapse prevention;
- (ee) counseling and recovery support services;
- (ff) staffing roles and considerations;
- (gg) diversion control; and
- (hh) other best practices, as identified by the Secretary.

(V) The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.

(VI) The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients.

(VII) The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate-dependent patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

(iii) The term "qualifying practitioner" means—

(I) a qualifying physician, as defined in clause (ii); or

(II) during the period beginning on July 22, 2016, and ending on October 1, 2021, a qualifying other practitioner, as defined in clause (iv).

(iv) The term "qualifying other practitioner" means a nurse practitioner or physician assistant who satisfies each of the following:

- (I) The nurse practitioner or physician assistant is licensed under State law to prescribe schedule III, IV, or V medications for the treatment of pain.
- (II) The nurse practitioner or physician assistant has—

(aa) completed not fewer than 24 hours of initial training addressing each of the topics listed in clause (ii)(IV) (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Nurses Credentialing Center, the American Psychiatric Association, the American Association of Nurse Practitioners, the American Academy of Physician Assistants, or any other organization that the Secretary determines is appropriate for purposes of this subclause; or

(bb) has such other training or experience as the Secretary determines will demonstrate the ability of the nurse practitioner or physician assistant to treat and manage opiate-dependent patients.

(III) The nurse practitioner or physician assistant is supervised by, or works in collaboration with, a qualifying physician, if the nurse practitioner or physician assistant is required by State law to prescribe medications for the treatment of opioid use disorder in collaboration with or under the supervision of a physician.

The Secretary may, by regulation, revise the requirements for being a qualifying other practitioner under this clause.

(H)(i) In consultation with the Administrator of the Drug Enforcement Administration, the Administrator of the Substance Abuse and Mental Health Services Administration, the Director of the National Institute on Drug Abuse, and the Commissioner of Food and Drugs, the Secretary shall issue regulations (through notice and comment rulemaking) or issue practice guidelines to address the following:

(I) Approval of additional credentialing bodies and the responsibilities of additional credentialing bodies.

(II) Additional exemptions from the requirements of this paragraph and any regulations under this paragraph.

(III) Such other elements of the requirements under this paragraph as the Secretary determines necessary for purposes of implementing such requirements.

Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.

(ii) Not later than 18 months after the date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act,<sup>1</sup> the Secretary shall update the treatment improvement protocol containing best practice guidelines for the treatment of opioid-dependent patients in office-based settings. The Secretary shall update such protocol in consultation with experts in opioid use disorder research and treatment.

<sup>1</sup> See References in Text note below.

(I) Notwithstanding section 903 of this title, nothing in this paragraph shall be construed to preempt any State law that—

(i) permits a qualifying practitioner to dispense narcotic drugs in schedule III, IV, or V, or combinations of such drugs, for maintenance or detoxification treatment in accordance with this paragraph to a total number of patients that is more than 30 or less than the total number applicable to the qualifying practitioner under subparagraph (B)(iii)(II) if a State enacts a law modifying such total number and the Attorney General is notified by the State of such modification; or

(ii) requires a qualifying practitioner to comply with additional requirements relating to the dispensing of narcotic drugs in schedule III, IV, or V, or combinations of such drugs, including requirements relating to the practice setting in which the qualifying practitioner practices and education, training, and reporting requirements.

#### **(h) Applicants for distribution of list I chemicals**

The Attorney General shall register an applicant to distribute a list I chemical unless the Attorney General determines that registration of the applicant is inconsistent with the public interest. Registration under this subsection shall not be required for the distribution of a drug product that is exempted under clause (iv) or (v) of section 802(39)(A) of this title. In determining the public interest for the purposes of this subsection, the Attorney General shall consider—

(1) maintenance by the applicant of effective controls against diversion of listed chemicals into other than legitimate channels;

(2) compliance by the applicant with applicable Federal, State, and local law;

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

#### **(i) Registration to manufacture certain controlled substances for use only in a clinical trial**

(1) For purposes of registration to manufacture a controlled substance under subsection (d) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

#### **(j) Emergency medical services that administer controlled substances**

##### **(1) Registration**

For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (f).

##### **(2) Option for single registration**

In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

##### **(3) Hospital-based agency**



If a hospital-based emergency medical services agency is registered under subsection (f), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

**(4) Administration outside physical presence of medical director or authorizing medical professional**

Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

- (A) authorized by the law of the State in which it occurs; and
- (B) pursuant to—
  - (i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or
  - (ii) a verbal order that is—
    - (I) issued in accordance with a policy of the agency; and
    - (II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—
      - (aa) in the case of a mass casualty incident; or
      - (bb) to ensure the proper care and treatment of a specific patient.

**(5) Delivery**

A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

- (A) designates the unregistered location for such delivery; and
- (B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

**(6) Storage**

A registered emergency medical services agency may store controlled substances—

- (A) at a registered location of the agency;
- (B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or
- (C) in an emergency medical services vehicle used by the agency that is—
  - (i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or
  - (ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

**(7) No treatment as distribution**

The delivery of controlled substances by a registered emergency medical services agency pursuant to this subsection shall not be treated as distribution for purposes of section 828 of this title.

**(8) Restocking of emergency medical services vehicles at a hospital**

Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 828 of this title, provided all of the following conditions are satisfied:

- (A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).
- (B) The hospital maintains a record of such delivery to the agency in accordance with section 827 of this title.
- (C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

**(9) Maintenance of records**

**(A) In general**

A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 827 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 827(c)(1)(B) of this title.

**(B) Requirements**

Such records—

- (i) shall include records of deliveries of controlled substances between all locations of the agency; and
- (ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

**(10) Other requirements**

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

- (A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;
- (B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;
- (C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and
- (D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

**(11) Regulations**

The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

- (i) the types of locations that may be designated under such paragraph; and
- (ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

- (i) shortages of such substances;
- (ii) a public health emergency; or
- (iii) a mass casualty event.

## (12) Rule of construction

Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this subchapter to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

## (13) Definitions

In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

- (i) who is registered under this chapter;
- (ii) who is acting within the scope of the registration; and
- (iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that—

- (i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;
- (ii) provides emergency medical services by ground, air, or otherwise; and
- (iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (f) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means—

- (i) an emergency medical services agency that is registered pursuant to this subsection; or
- (ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (f).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (f), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

## (k) "Factors as may be relevant to and consistent with the public health and safety" defined

In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 801 of this title.

( Pub. L. 91-513, title II, §303, Oct. 27, 1970, 84 Stat. 1253 ; Pub. L. 93-281, §3, May 14, 1974, 88 Stat. 124 ; Pub. L. 95-633, title I, §109, Nov. 10, 1978, 92 Stat. 3773 ; Pub. L. 98-473, title II, §511, Oct. 12, 1984, 98 Stat. 2073 ; Pub. L. 103-200, §3(c), Dec. 17, 1993, 107 Stat. 2336 ; Pub. L. 106-310, div. B, title XXXV,



§3502(a), Oct. 17, 2000, 114 Stat. 1222 ; Pub. L. 107-273, div. B, title II, §2501, Nov. 2, 2002, 116 Stat. 1803 ; Pub. L. 109-56, §1(a), (b), Aug. 2, 2005, 119 Stat. 591 ; Pub. L. 109-177, title VII, §712(a)(3), Mar. 9, 2006, 120 Stat. 263 ; Pub. L. 109-469, title XI, §1102, Dec. 29, 2006, 120 Stat. 3540 ; Pub. L. 110-425, §3(b), Oct. 15, 2008, 122 Stat. 4824 ; Pub. L. 114-89, §3, Nov. 25, 2015, 129 Stat. 701 ; Pub. L. 114-145, §2(a)(1), Apr. 19, 2016, 130 Stat. 354 ; Pub. L. 114-198, title III, §303(a)(1), (b), July 22, 2016, 130 Stat. 720 , 723 ; Pub. L. 115-83, §2, Nov. 17, 2017, 131 Stat. 1267.)

#### References in Text

Schedules I, II, III, IV, and V, referred to in subsecs. (a) to (f), (g)(2), and (j)(1), (4), are set out in section 812(c) of this title.

This subchapter, referred to in subsecs. (f) and (j)(12)(A), was in the original "this title", meaning title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242 , and is popularly known as the "Controlled Substances Act". For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (g)(2)(C)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040 , as amended, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

The date of enactment of the Opioid Use Disorder Treatment Expansion and Modernization Act, referred to in subsec. (g)(2)(H)(ii), probably means the date of enactment of Pub. L. 114-198, known as the Comprehensive Addiction and Recovery Act of 2016, which was approved July 22, 2016. The Opioid Use Disorder Treatment Expansion and Modernization Act was H.R. 4981 of the 114th Congress, as introduced on Apr. 18, 2016. Amendatory provisions of H.R. 4981 were incorporated into Pub. L. 114-198, but no such Short Title was enacted.

This chapter, referred to in subsec. (j)(13)(A)(i), was in the original "this Act", meaning Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1236 . For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

#### Amendments

**2017**—Subsecs. (j), (k). Pub. L. 115-83 added subsec. (j) and redesignated former subsec. (j) as (k).

**2016**—Subsec. (g)(2)(B). Pub. L. 114-198, §303(a)(1)(A), added cls. (i) to (iii) and struck out former cls. (i) to (iii) which read as follows:

"(i) The practitioner is a qualifying physician (as defined in subparagraph (G)).

"(ii) With respect to patients to whom the practitioner will provide such drugs or combinations of drugs, the practitioner has the capacity to refer the patients for appropriate counseling and other appropriate ancillary services.

"(iii) The total number of such patients of the practitioner at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The Secretary may by regulation change such total number."

Subsec. (g)(2)(D)(ii). Pub. L. 114-198, §303(a)(1)(B)(i), substituted "Upon receiving a determination from the Secretary under clause (iii) finding that a practitioner meets all requirements for a waiver under subparagraph (B)" for "Upon receiving a notification under subparagraph (B)".

Subsec. (g)(2)(D)(iii). Pub. L. 114-198, §303(a)(1)(B)(ii), inserted "and shall forward such determination to the Attorney General" after "a waiver under subparagraph (B)" and substituted "assign the practitioner" for "assign the physician".

Subsec. (g)(2)(G)(ii)(I). Pub. L. 114-198, §303(a)(1)(C)(i), amended subcl. (I) generally. Prior to amendment, subcl. (I) read as follows: "The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties."

Subsec. (g)(2)(G)(ii)(II). Pub. L. 114-198, §303(a)(1)(C)(ii), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: "The physician holds an addiction certification from the American Society of Addiction Medicine."

Subsec. (g)(2)(G)(ii)(III). Pub. L. 114-198, §303(a)(1)(C)(iii), struck out "subspecialty" before "board certification".

Subsec. (g)(2)(G)(ii)(IV). Pub. L. 114-198, §303(a)(1)(C)(iv), amended subcl. (IV) generally. Prior to amendment, subcl. (IV) read as follows: "The physician has, with respect to the treatment and management of opiate-dependent patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause."

Subsec. (g)(2)(G)(iii), (iv). Pub. L. 114-198, §303(a)(1)(C)(v), added cls. (iii) and (iv).

Subsec. (g)(2)(H)(i)(III). Pub. L. 114-198, §303(a)(1)(D)(i), added subcl. (III).

Subsec. (g)(2)(H)(ii). Pub. L. 114-198, §303(a)(1)(D)(ii), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: "Not later than 120 days after October 17, 2000, the Secretary shall issue a treatment improvement protocol containing best practice guidelines for the treatment and maintenance of opiate-dependent patients. The Secretary shall develop the protocol in consultation with the Director of the National Institute on Drug Abuse, the Administrator of the Drug Enforcement Administration, the Commissioner of Food and Drugs, the Administrator of the Substance Abuse and Mental Health Services Administration and other substance abuse disorder professionals. The protocol shall be guided by science."

Subsec. (g)(2)(I), (J). Pub. L. 114-198, §303(b), added subpar. (I) and struck out former subpars. (I) and (J) which limited a State's ability to preclude a practitioner from dispensing or prescribing certain approved drugs and provided the effective date of the paragraph and authorized the Secretary and the Attorney General to make certain determinations.

Subsec. (j). Pub. L. 114-145 added subsec. (j).

**2015**—Subsec. (i). Pub. L. 114-89 added subsec. (i).

**2008**—Subsec. (f). Pub. L. 110-425, in introductory provisions, inserted "and shall modify the registrations of pharmacies so registered to authorize them to dispense controlled substances by means of the Internet" after "schedule II, III, IV, or V" and substituted "or such modification of registration if the Attorney General determines that the issuance of such registration or modification" for "if he determines that the issuance of such registration".

**2006**—Subsec. (g)(2)(B)(iii). Pub. L. 109-469, §1102(1), substituted "unless, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients. A second notification under this clause shall contain the certifications required by clauses (i) and (ii) of this subparagraph. The" for "except that the".

Subsec. (g)(2)(J)(i). Pub. L. 109-469, §1102(2)(A), substituted "thereafter." for "thereafter except as provided in clause (iii) (relating to a decision by the Secretary or the Attorney General that this paragraph should not remain in effect)."

Subsec. (g)(2)(J)(ii). Pub. L. 109-469, §1102(2)(B), substituted "December 29, 2006" for "October 17, 2000" in introductory provisions.

Subsec. (g)(2)(J)(iii). Pub. L. 109-469, §1102(2)(C), substituted "subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective" for "this paragraph should not remain in effect, this paragraph ceases to be in effect".

Subsec. (h). Pub. L. 109-177 substituted "clause (iv) or (v) of section 802(39)(A) of this title" for "section 802(39)(A)(iv) of this title" in introductory provisions.

**2005**—Subsec. (g)(2)(B)(iii). Pub. L. 109-56, §1(b), substituted "The total" for "In any case in which the practitioner is not in a group practice, the total".

Subsec. (g)(2)(B)(iv). Pub. L. 109-56, §1(a), struck out cl. (iv) which read as follows: "In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable



number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have."

**2002**—Subsec. (g)(2)(I). Pub. L. 107-273, §2501(1), which directed the substitution of "on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs," for "on October 17, 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs," was executed by making the substitution for the phrase which in the original began with "on the date of the enactment of the Drug Addiction Treatment Act of 2000," rather than the editorial translation "on October 17, 2000," to reflect the probable intent of Congress.

Subsec. (g)(2)(I)(i). Pub. L. 107-273, §2501(2), which directed the substitution of "the date referred to in subparagraph (I)," for "October 17, 2000," was executed by making the substitution for text which in the original read "the date of the enactment of the Drug Addiction Treatment Act of 2000," rather than the editorial translation "October 17, 2000," to reflect the probable intent of Congress.

**2000**—Subsec. (g). Pub. L. 106-310 designated existing provisions as par. (1), substituted "Except as provided in paragraph (2), practitioners who dispense" for "Practitioners who dispense", redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

**1993**—Subsec. (h). Pub. L. 103-200 added subsec. (h).

**1984**—Subsec. (f). Pub. L. 98-473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

**1978**—Subsec. (f). Pub. L. 95-633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

**1974**—Subsec. (g). Pub. L. 93-281 added subsec. (g).

#### Effective Date of 2008 Amendment

Amendment by Pub. L. 110-425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110-425, set out as a note under section 802 of this title.

#### Effective Date of 2005 Amendment

Pub. L. 109-56, §1(c), Aug. 2, 2005, 119 Stat. 591, provided that: "This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005]."

#### Effective Date of 1993 Amendment

Amendment by Pub. L. 103-200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103-200, set out as a note under section 802 of this title.

#### Effective Date of 1978 Amendment

Amendment by Pub. L. 95-633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95-633, set out as an Effective Date note under section 801a of this title.

#### Effective Date

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of Pub. L. 91-513, set out as a note under section 801 of this title.

#### Update Regulations

Pub. L. 114-198, title III, §303(c), July 22, 2016, 130 Stat. 723, provided that: "Not later than 18 months after the date of enactment of this Act [July 22, 2016], the Attorney General and the Secretary of Health and Human Services, as appropriate, shall update regulations regarding practitioners described in subsection (a)(3)(B) (vii) (as amended by this section) [probably means subsec. (a)(3)(B)(vii) of this section], set out as a note below] to include nurse practitioners and physician assistants to ensure the quality of patient care and prevent diversion."

#### Reports to Congress

Pub. L. 114-198, title III, §303(a)(3), July 22, 2016, 130 Stat. 722, provided that:

"(A) In general.—Not later than 3 years after the date of enactment of this Act [July 22, 2016] and not later than 3 years thereafter, the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration and experts in opioid use disorder research and treatment, shall—

"(i) perform a thorough review of the provision of opioid use disorder treatment services in the United States, including services provided in opioid treatment programs and other specialty and nonspecialty settings; and

"(ii) submit a report to the Congress on the findings and conclusions of such review.

"(B) Contents.—Each report under subparagraph (A) shall include an assessment of—

"(i) compliance with the requirements of section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), as amended by this section;

"(ii) the measures taken by the Secretary of Health and Human Services to ensure such compliance;

"(iii) whether there is further need to increase or decrease the number of patients a practitioner, pursuant to a waiver under section 303(g)(2) of the Controlled Substances Act (21 U.S.C. 823(g)(2)), is permitted to treat;

"(iv) the extent to which, and proportions with which, the full range of Food and Drug Administration-approved treatments for opioid use disorder are used in routine health care settings and specialty substance use disorder treatment settings;

"(v) access to, and use of, counseling and recovery support services, including the percentage of patients receiving such services;

"(vi) changes in State or local policies and legislation relating to opioid use disorder treatment;

"(vii) the use of prescription drug monitoring programs by practitioners who are permitted to dispense narcotic drugs to individuals pursuant to a waiver described in clause (iii);

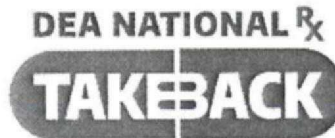
"(viii) the findings resulting from inspections by the Drug Enforcement Administration of practitioners described in clause (vii); and

"(ix) the effectiveness of cross-agency collaboration between [the] Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment."

#### Provisional Registration

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91-513, set out as a note under section 822 of this title.





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